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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,309	07/29/2003	J. R. Patil	U 014742-0	6603

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LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,309	PATIL ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on February 14, 2008 has been entered. Claim 27 has been amended. No claims have been canceled or added. Accordingly, claims 20, 21 and 24-27 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112- first paragraph, enablement, biological deposit

Claims 20, 21 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Biological deposit required

The invention appears to employ a novel microorganism from which the claimed bioemulsifier is derived. Because the microorganism is essential to the claimed invention (the bioemulsifier cannot be obtained and purified without Applicants' strain of *Acinetobacter junii*), it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microorganism, isolated from a human, and the method of

isolation are not fully disclosed, nor is the source of the organism publicly known and freely available. The specification does not disclose a repeatable process to obtain the microorganism, and it is not apparent if the microorganism is readily available to the public. The enablement requirements of 35 USC §112 may be satisfied by a deposit of the microorganism. Accordingly, it is deemed that a deposit of this microorganism should have been made in accordance with 37 C.F.R. 1.801-1.809.

If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Additionally, amendment of the specification to recite the date of the deposit, the

complete name and address of the depository, and the accession number of the deposited cell line is required.

Claim Rejections - 35 USC § 112, first paragraph

Claims 20 and 21 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 20 recites a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after 140 hours at 10º C. Claim 21 recites a bioemulsifier from any *Acinetobacter junii* that has this same property. The claims recite a bioemulsifier that is described by one functional limitation only, without the recitation of any structural features. The specification discloses only one such bioemulsifier, the one from Applicants' strain SC-14. This rejection has been discussed in the previous Office actions.

Applicants assert that the enclosed article by Seifert et al. discloses that not all strains of *Acinetobacter* are isolated from human skin, that the properties of *Acinetobacter* from human skin are unique because of the environment of human skin and that an *Acinetobacter* from human skin is clearly described.

In reply, Seifert et al. do disclose that *Acinetobacter* strains may be isolated from many sources besides human skin- soil, water, dry environments, food and animals (see p. 2819, first paragraph). The different strains may indeed have different properties, as they grow in different environments. But, the rejection is not that all *Acinetobacter* strains appear to be the same. The rejection is that the claimed bioemulsifier is defined by only one functional property, which, as discussed below, is unclear and ambiguous in multiple ways. No structural features are recited that would allow one of skill in the art to determine whether or not a bioemulsifier from an

Acinetobacter strain in the prior art is the same or different. Additionally, the claims recite a genus of bioemulsifiers, while the specification discloses only one species, that from Applicants' strain SC-14. Seifert et al. do not describe additional species of this genus. Thus, the claimed genus is not adequately described.

In view of the foregoing, the rejection of record is maintained.

Claims 20 and 21 are also again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioemulsifier from SC14, does not reasonably provide enablement for a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after 140 hours at 10º C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection has been discussed in the previous Office action.

Applicants' response to this rejection is the same as their response to the written description rejection above. Applicants assert that the enclosed article by Seifert et al. discloses that not all strains of *Acinetobacter* are isolated from human skin, that the properties of *Acinetobacter* from human skin are unique because of the environment of human skin and that an *Acinetobacter* from human skin is clearly enabled.

In reply, as noted above, Seifert et al. do disclose that *Acinetobacter* strains may be isolated from many sources besides human skin- soil, water, dry environments, food and animals (see p. 2819, first paragraph). The different strains may indeed have different properties, as they grow in different environments. But, the rejection is not that all *Acinetobacter* strains appear to be the same. The rejection is that a genus of *Acinetobacter* bioemulsifiers is claimed, but only one species of this genus is disclosed (a procedure for the partial purification of which is disclosed on p. 11 of the specification). The specification provides no guidance for

isolating additional species of the claimed genus. Thus, it cannot be predicted that a number of additional species constituting the claimed genus exist. It would be undue experimentation to practice the full scope of the claims, particularly in view of the lack of guidance and predictability, because the type of experimentation required to practice the claimed invention is on a random make-and-test-for-function basis, and, as a result of all of the foregoing, the amount of experimentation required to identify additional species of the claimed genus is undue. Applicants' response has not addressed the enablement rejection.

Therefore, the rejection of record is maintained.

Claim Rejections - 35 USC § 112, second paragraph

Claims 20, 21, 24 and 27 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been discussed in the previous Office action.

To reiterate, it cannot be determined if 35% stability refers to the percentage of an emulsion that remains in one phase or the percentage of the emulsifier that remains intact without decomposing. Additionally, the ratio of oil or fat to water in the emulsion that has 35% stability and the nature of the oily phase and the aqueous phase are not defined. Consequently, the metes and bounds of the claims are indefinite.

Applicants assert that, in the claimed bioemulsifier, 35% of the emulsification activity is retained after 140 hours. Applicants have submitted a copy of their 2001 article in the Journal of Applied Microbiology to discuss emulsion stability.

In reply, Applicants have not indicated which portion of the article discusses emulsion stability, what the article says about emulsion stability, or how the article clarifies the meaning of

the claims. Most importantly, Applicants have not amended the claims so that their meaning is clear. That is what is required. On p. 291, left col., an emulsification assay is described in which 3 ml of spent culture medium or "a suitably diluted emulsifier preparation" was mixed with 0.5 ml of a test oil, vortexed and incubated at 37 °C. The absorbance of the aqueous phase at 400 nm was measured over time. But, this assay does not shed light on the meaning of the instant claims. Appropriate correction is still required. Applicants may, for example, delete the "wherein" clause or amend it to recite a specific mixture comprising specific amounts of a specific aqueous phase, a specific oil phase and the bioemulsifier, in which 35% of the bioemulsifier or 35% of the emulsion remains intact. The rejection of record is maintained.

As previously discussed, claim 24 recites the limitations "esterase activity," "esterase" and "fermentation medium." There is insufficient antecedent basis for these limitations in the claim, as claim 27 does not recite an esterase or a fermentation medium. Additionally, claim 24 is indefinite and confusing because the relationship between the esterase and the bioemulsifier is not clear. Is the esterase part of the protein component of the bioemulsifier? The claim must be amended to clarify this point. Appropriate correction is required.

Applicants assert that the esterase is a secreted enzyme that is needed for the release of the bioemulsifier from the bacterial cell, but that the esterase is not part of the protein component.

In reply, Applicants have not amended claim 24 to clarify its meaning, particularly if the esterase is not part of the bioemulsifier. Applicants' explanations with regard to the esterase do not clarify the meaning of the claim. Appropriate correction of the claim is still required. The claims are drawn to a bioemulsifier, and the esterase, apparently, does not materially change the bioemulsifier. Claim 24 may be replaced by an independent claim reciting the same bioemulsifier as in claim 27, wherein the bioemulsifier is released from the *Acinetobacter* cells

by the action of an esterase, wherein the esterase is also released from the cells.

Claim Rejections - 35 USC § 102/103

Claim 20 is again rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gutnik et al. (US 4,230,801). Gutnik discloses a bioemulsifier produced by *Acinetobacter* (species not specified) comprising protein, polysaccharide and lipid that appears to be the same as Applicants' claimed bioemulsifier, as the Office does not have the facilities and resources to determine whether or not the two bioemulsifiers are different. Applicants have not shown that the two bioemulsifiers are different. This rejection has been discussed in the previous Office actions.

Applicants assert that the bioemulsifier of Gutnik et al. is different from theirs, because Gutnik et al. disclose an alpha-emulsan and a beta-emulsan. Applicants describe the various lipids and their relative percentages by weight in the emulsans of Gutnik et al.

In reply, Applicants have not amended the claim to define their invention over Gutnik et al. As previously discussed, Applicants have not claimed their bioemulsifier by its structure, but by one functional property, the retention of 35% stability after 140 hours at 10 °C. It cannot be determined by the Office whether or not one or both emulsans of Gutnik et al. also have this property. Thus, the claimed bioemulsifier and the prior art bioemulsifier(s) appear to be the same.

In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 103

Claims 20 and 21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnik et al. (US 4,230,801); Shabtai et al. (“Emulsan: a case study of microbial capsules as

industrial products," Symposium: Extracellular Microbial Polysaccharides, chap. 19, pp. 291-307, publication date not provided); and Zosim et al. (Biotechnology and Bioengineering 24:281-292, 1982). This rejection has been discussed in the previous Office actions.

To reiterate, the bioemulsifiers of Gutnik et al. and Shabtai et al. appear to be the same as Applicants' claimed bioemulsifier, and Applicants have not shown that the two are different. Zosim discloses the stability of the bioemulsifier of Gutnik et al., which appears to be the same as that of Applicants' bioemulsifier.

Applicants assert that bioemulsifiers from dermal *Acinetobacter* strains have higher activity than bioemulsifiers from soil or burn wound isolates. Applicants assert that the *Acinetobacter* of Shabtai et al. and Zosim et al. are not isolated from skin, and therefore, these references cannot be combined with Gutnik et al.

In reply, similarly to the above rejection, Applicants have not amended the claim to define their invention over the cited art. As previously discussed, Applicants have not claimed their bioemulsifier by its structure, but by one functional property, the retention of 35% stability after 140 hours at 10 ºC. It cannot be determined by the Office whether or not the bioemulsifier of Gutnik et al. and the bioemulsifier of Shabtai et al. also have this property. Thus, the claimed bioemulsifier and the prior art bioemulsifiers, all of which contain protein, lipids and polysaccharides from *Acinetobacter*, appear to be the same. Because the prior art bioemulsifiers appear to be the same as that of Applicants, the references may be combined.

In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The

examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2007-03-06

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652